

AMENDMENT UNDER 37 C.F.R. § 1.116  
U.S. Application No. 10/083,413

Q63391

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

- C1
1. (currently amended): A solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:
    - (a) a therapeutically effective amount of at least one herbal active agent or homeopathic active agent, wherein the herbal active agent is selected from the group consisting of a bioactive herb extract, a tincture, an essential oil and mixtures thereof; and
    - (b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition.
  2. (currently amended): A solid composition according to claim 1 wherein said composition is in the form of a disc of ~~2-15~~ 2 to 15 mm diameter and 0.4 to 2.3 mm thick that adheres to oral mucosal tissue for at least 30 minutes.
  3. (currently amended): A solid composition according to claim 1 wherein said composition is in the form of a disc of ~~5-11~~ 5 to 11 mm diameter and 1 to 2 mm thick with tissue adherence of at least 1 hour.
  4. (previously presented): A composition according to claim 1, wherein the herbal active agent is at least one selected from the group consisting of an anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, and an antiparasite agent.

AMENDMENT UNDER 37 C.F.R. § 1.116  
U.S. Application No. 10/083,413

Q63391

Cont  
C1  
5. (canceled).

6. (previously presented): A composition according to claim 1, wherein the herbal active agent or homeopathic active agent is at least one selected from the group consisting of Gotu Kola, Echinacea, Salvia officinalis, Hypericum, Myrrh, Camphoria, Uncaria, Elder, Plantago, Baptisia, Calendula, Phytolacca, Catechu black, Coneflower, Krameria, Tsuga, grape fruit seed extract, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Krameria, Matricaria, Mallow, Propolis, Sage, berberine from hydrastis canadensis L., plant family Berberidaceae, gentian from the gentianaceae family of plants for the treatment of fungal infections, monoterpenes of three unsaturations, Taraxacum extract, Lonicera flower extract, Scutellaria root extract, Gardenia fruit extract, Pulsatilla root extract, Pueraria root extract, and Radix gentianae Longdancao antifungal agent.

7. (currently amended): The composition of claim 5 1, wherein the herbal active agent is at least one essential oil selected from the group consisting of citronella oil, lemon oil, citron oil, pomelo peel oil, cedarwood oil, juniper berries oil, lemon basil oil, Rosmarinus officinalis oil, cinnamon oil, cajeput oil, eucalyptus oil, fennel oil, geranium oil, girofle oil, lavender oil, clove oil, spearmint oil, myrte oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, and tea-tree oil.

8. (currently amended): The composition of claim 5 1, wherein the herbal active agent is at least one essential oil selected from the group consisting of cinnamon oil, tea-tree oil and citronella oil.

AMENDMENT UNDER 37 C.F.R. § 1.116  
U.S. Application No. 10/083,413

Q63391

Cost  
C1

9. (previously presented): A composition according to claim 6, wherein the herbal active agent comprises at least one monoterpene with three unsaturations.

10. (currently amended): A composition according to claim 5 1, wherein the herbal active agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of limonene and at least one of myrcene,  $\alpha$ -pinene,  $\beta$ -pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene.

11. (previously presented): A composition according to claim 9, wherein said monoterpenes with three unsaturations is at least one citrus oil selected from the group consisting of lemon, pomelo and citron.

12. (original): A composition according to claim 6, further comprising a salt selected from the group consisting of  $MgBr_2$ , NaCl, KCl and mixtures thereof.

13. (previously presented): A composition according to claim 6, further comprising Carnallite.

14. (previously presented): A composition according to claim 13, wherein said Carnallite is present in an amount of about 5-50% wt/wt based on the amount of the at least one herbal active agent or homeopathic active agent.

15. (previously presented): The composition of claim 1, further comprising a non-herbal active agent selected from the group consisting of anesthetic agent, analgesics, steroidal and non-steroidal anti-inflammatory agents, antihistaminic or antiallergics, steroids, antimicrobial drugs, vitamins, enzymes, anti-allergic drugs, antipyretics, antimalarial, antiulcer drugs, peptides, DNA plasmid and antisense based therapeutic agents.

**AMENDMENT UNDER 37 C.F.R. § 1.116**

U.S. Application No. 10/083,413

**Q63391**

Cost  
C1

16. (previously presented): The composition of claim 15, wherein the anesthetic agent is selected from the group consisting of at least one base or acid-addition salt of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocaine, chlorprocaine, tetracaine, bupivacaine, and etidocaine.

17. (previously presented): The composition of claim 15, wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, amphotericine B, nystatin, itraconazole, chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes.

18. (previously presented): The composition of claim 4, further comprising Carnallite or a salt of Carnallite which improves the activity of the herbal active agents.

19. (previously presented): The composition of claim 4, wherein the herbal active agent consists of a mixture of natural or synthetic monoterpenes with three unsaturations selected from the group consisting of limonene, myrcene, pinenes, sabinene, and terpinene.

20. (previously presented): The composition of claim 15 comprising a citron oil and Carnallite salt at a weight ratio between 1:10 to 1:1.

21. (previously presented): The composition of claim 15 comprising a citron oil and Carnallite salt at a weight ratio between 1:10 to 1:1 and a local anesthetic selected from the group consisting of lidocaine, benzocaine, and bupivacaine.

22. (previously presented): The composition of claim 1, wherein the solid bioadhesive carrier is selected from a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer and mixtures thereof.

**AMENDMENT UNDER 37 C.F.R. § 1.116**

U.S. Application No. 10/083,413

**Q63391**Cont  
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23. (previously presented): The composition of claim 22 wherein said polyhydric polymer comprises at least one member selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, carboxymethyl cellulose, dextran, arabinogalactan, pullulan, guar-gum, hyaluronic acid, pectins, starch derivatives, acrylic acid polymers, polymers of acrylic acid esters, acrylic acid copolymers, polymers of vinyl alcohols, alkoxy polymers, polyethylene oxide polymers, polyethers, and mixtures thereof.

24. (previously presented): A composition according to claim 22 in the form of a tablet wherein said composition additionally contains one or more members selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzyme inhibitors, and lubricants.

25. (previously presented): A composition according to claim 24 wherein said enhancers are selected from salts of bile acids and limonene.

26. (previously presented): A composition according to claim 22 wherein said solid bioadhesive carrier is selected from polyacrylic acid polymers lightly crosslinked with a polyalkenyl polyether, carboxymethylcellulose, hydroxymethylcellulose and mixtures thereof.

27. (withdrawn): A solid self-bioadhesive composition for a topical application that adheres to the oral mucosal tissue comprising:

(a) a combination of an anti-inflammatory, anesthetics agent and an anti-microbial agent; and

(b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition.

AMENDMENT UNDER 37 C.F.R. § 1.116  
U.S. Application No. 10/083,413

Q63391

Cont  
C1

28. (withdrawn): A solid -bioadhesive composition of Claim 27, wherein combinations consisting of: anti-microbials - chlorhexidine, povidone-iodine, picoxidine, iodoform, triclosan; anti-biotics: tetracycline, sulfadiazine, ofloxacin, trimethoprim; anti-fungal: amphotericine B, nystatin, miconazole, triazoles; anesthetics/analgesics: lidocaine, benzocaine, tetracaine, codeine, bupivacaine, cocaine, anti-microbial - chlorhexidine, povidone-iodine, picoxidine, iodoform, triclosan; anti-biotics: tetracycline, sulfadiazine, ofloxacin, trimethoprim; anti-fungal: amphotericine B, nystatin, miconazole, triazoles; antiproliferative /anticollagenase agents; anti-puritic: camphor, phenol, menthol; anti-viral: acyclovir, acridineamine; anti-ulcerative: acetoxolone, sucralfate, teprenone, omeprazole; Salts: sodium fluoride, Carnallite and its individual salts.

29. (withdrawn): A method for the preparation of a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue comprising the following steps:

(c) forming a solid powder of a herbal active agent by drying the herbal liquid extract with an inert component;

(d) mixing the herbal active powder with the adhesive inert powders and lubricants; and

(e) compressing said mixture into tablets of the desired size and shape.

30. (withdrawn): A method according to claim 28, wherein said mixture is compressed into a disc form of 2-15 mm diameter and 0.4 to 2.3 mm thick that adheres to oral mucosal tissue for at least 30 minutes or more.

**AMENDMENT UNDER 37 C.F.R. § 1.116**

U.S. Application No. 10/083,413

**Q63391**

Good  
C1

31. (withdrawn): A method according to claim 28, wherein said mixture is compressed into a disc form of 5-11mm diameter and 1 to 2 mm thick with tissue adherence of least 1 hour.

32. (withdrawn): A method for topical oral treatment, consisting of administering to a patient a composition comprising a terpenoid oil consisting of at least 65% limonene oil in combination with a suitable solid self-bioadhesive carrier.

33. (withdrawn): A method for treating and/or preventing, oral mucositis (stomatitis), aphthous lesions, gingivitis in a patient, comprising administering a composition of claim 1.

34. (withdrawn): A method for reducing the depth of periodontal pockets in a patient, comprising administering a composition of claim 1.

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